Morges, Switzerland) is polymer- and carrier-free, releases Biolimus A9 into the vessel wall over a period of 4 weeks, and then technically becomes a BMS.

Methods 2,466 pts at high bleeding risk from 68 centers in Europe, Asia, and Canada were enrolled over an 18 months period in a double-blinded randomized 1:1 comparison of the Gazelle™ BMS vs. the BioFreedom DCS (both Biosensors, Morges, CH) with a 1 month course of DAPT only in both arms. At 1 year, the primary endpoints are: safety: a composite of cardiovascular death, MI and stent thrombosis, and efficacy: the rate of ci-TLR.

Current results In the trial population, the most frequently used inclusion criteria were: advanced age (64%), need for long term oral anticoagulation (36%), anemia, recent bleeding or transfusion (20%), renal insufficiency (18%), planned surgery (15%) and concomitant cancer (9%). When compared to those included in 'all-comer' trials, pts were markedly older (75 years) and had more co-morbidiites (diabetes 33%, atrial fibrillation 33%, peripheral vascular disease 15%, heart failure 13%, prior stroke 9% and COPD 11%) 1.5 lesions/pts were treated and 1.7 stents/pts were implanted for a total stent length of 32mm/patient. Technical procedure success was 95%. 71% of pts were discharged on DAPT alone, 27% of DAPT+oral anticoagulation and 2% on a single antiplatelet agent + oral anticoagulation.

Conclusion The trial focuses on a never previously studied high bleeding risk population characterized by advanced age and more comorbid conditions. It is the 1st evaluation of a DCS with clinical endpoints and comprises the shortest ever DAPT course with an active stent to be evaluated for both safety and efficacy.

The author hereby declares no conflict of interest

0197

Angiographically visible distal embolization is not linked with culprit lesion but with clinical characteristics

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Despite the recent improvements in percutaneous coronary intervention (PCI), angiographically visible distal embolization (AVDE) complicates 6 to 18% of ST elevation myocardial infarction (STEMI) treated with PCI, and is associated with poor clinical outcomes. Culprit lesion characteristics have been proved to be the main predictive factor of AVDE. But data regarding clinical characteristics predicting AVDE are lacking. We aimed to identify predictors of AVDE complicating PCI in STEMI management. 769 consecutive patients admitted for STEMI who underwent PCI were included. Clinical, angiographic and therapeutics characteristics were assessed for each patien. AVDE was defined as an abrupt vessel closure occurring at any point during the PCI procedure and that was not present at baseline. Thrombectomy was used only when thrombolysis in myocardial infarction flow was ≤2. AVDE occurred in 112 (14.5%) patients. Patients with AVDE were older (67±14 vs. 63±14; with p=0.010), less likely to be men (59 vs. 74%; with p=0.002), have more frequently an artery diameter >3mm (36 vs. 28%: with p=0.046), a right coronary artery culprit lesion site (59 vs. 37%; with p<0.001) and more frequent thrombectomy (53 vs. 43%, with p=0.045). There was no difference regarding the other cardiovascular risk factors neither regarding syntax score. By multivariate analysis, age>60 (OR[95% CI]: 1.69 (1.09-2.64); p=0.020), female gender (OR[95% CI]:1.71(1.09-2.70); p=0.020), thrombectomy (OR[95% CI]:1.67(1.10-2.53); p=0.016) and the right coronary artery culprit lesion site (OR[95% CI]:2.52(2.1.66-3.81); p<0.001) were independent factors associated with AVDE. AVDE complicating PCI in STEMI management is frequent (14.5%). Strikingly we found no association between AVDE and culprit lesion characteristics. Conversely, clinical characteristics as age (>60 year-old), female gender, thrombectomy and the right coronary artery culprit lesion site are the most powerful predictive factors of AVDE.

The author hereby declares no conflict of interest

0453

Incidence of radiation-induced skin lesions after percutaneous coronary intervention

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Background Percutaneous coronary interventions (PCIs) use significant doses of ionizing radiation, especially when treating complex lesions. Ionizing radiation may lead to adverse acute or delayed skin lesions in this setting, for which the incidence is not well known.

Purpose To assess the incidence of radiation-induced skin lesions following PCI.

Methods We conducted a prospective, observational, single-centre study on the incidence of radiation-induced skin lesions at 3-5 days (acute) and at 6 months (subacute) after PCI with a dose-area product (DAP) ≥200Gy.cm^2, between 1 January and 31 December 2013. Patients consenting to participate were given information on potential skin lesions and were interviewed at 5-7 days and at 6 months after the PCI.

Results 1168 PCIs were performed; the radiation dose was available for 937 patients. Of these, 102 underwent PCI with DAP≥200Gy.cm^2. High body mass index (BMI; OR 6.2, 95% CI 2.8-13.9) and elective (vs emergency) procedures (OR 2.0, 95% CI 1.1-3.4) were independently associated with DAP ≥200Gy.cm^2. Three patients (3%, 95% CI 0.6-8.4) were diagnosed with acute lesions (DAP of 485Gy.cm^2, 205Gy.cm^2, and 201Gy.cm^2), two of whom also presented with subacute lesions following PCI with DAP of 485Gy.cm^2 (Fig.) and 205Gy.cm^2. One patient presented with a subacute lesion (DAP 280Gy.cm^2) only. Four patients presented with a skin lesion, which represents 4% (95% CI 1.1-9.7) of patients with DAP ≥200Gy.cm^2 and 0.4% (95% CI 0.1-1.1) of all the patients who underwent PCI, irrespective of DAP dose.

Conclusions The incidence of radiation-induced acute and subacute skin lesions developing after PCI in this single-centre study was 4% in patients with DAP ≥200Gy.cm^2, with a total incidence of 0.4%. These data may suggest the need for systematic assessment of skin lesions after high-dose radiation PCI.

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0107

Radiation exposure of the operator during coronary interventions: comparison of right radial, left radial and right femoral approach

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Background Because of a presumably increased incidence of long-term malignancy in interventional cardiologists, radiation exposure of the operator (ORE) during coronary interventions is of rising concern. A few studies comparing femoral to radial or right to left radial access have been published, but no data comparing the three access sites are available to our knowledge.

Purpose We sought to compare ORE by right femoral (RFA), right radial (RRA) and left radial (LRA) access during percutaneous catheterization for diagnostic coronary angiography (CA) with or without coronary angioplasty (PCI).

Methods From September 2014 to February 2015, all consecutive patients undergoing elective or emergency CA/PCI were prospectively included. Selection of the access site was left to the discretion of the cardiologist. ORE was measured using individual electronic radiation dosimeter badges positioned externally on the sternum. Radioprotection materials and equipment was similar for all procedures. Primary endpoint was ORE quantified as cumulative dose (CD) per dose-area product (DAP), in order to adjust for the administered radiation dose.

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